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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Atty. Docket: WALLACH=22

In re Application of:)
David WALLACH et al)
Appln. No.: 09/381,358)
Filed: September 30, 1999)
For: MODULATORS OF THE)
FUNCTION OF RECEPTORS ...)

Conf. No.: 3861

Abandoned

Washington, D.C.

October 30, 2003

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TECH CENTER 1600/2900

Atty. Docket: WALLACH=22A

In re Application of:)
David WALLACH et al)
Appln. No.: 09/927,458)
Filed: August 13, 2001)
For: MODULATORS OF FUNCTION OF)
RECEPTORS OF THE ...)

Conf. No.: 6865

Art Unit: 1644

Examiner: Phuong N. Huynh

Washington, D.C.

October 30, 2003

PETITION UNDER 37 C.F.R. §1.181 or §1.183

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
2011 South Clark Place
Crystal Plaza Two, Lobby, Room 1B03
Arlington, VA 22202

Sir:

Applicants hereby petition pursuant to 37 C.F.R.

§1.181 that the Director review and reverse the action of
Examiner Huynh dated August 19, 2003, ruling that claim 13 of
application number 09/927,458 is not entitled to the effective

filing date of PCT/IL98/00125 (filed March 19, 1998) because the

latter fails to have support for the recited depository accession number.

If it is deemed necessary that the now-abandoned prior application 09/381,358, the national stage of PCT/IL98/00125, be expressly amended to include the deposit number, applicants further petition pursuant to 37 C.F.R. §1.183 for suspension or waiver of any requirement of of the regulations that would prevent the Director from ruling that the claimed reference to depository no. I-2076 is entitled to the effective filing date of the parent. No such requirement of the regulations is a requirement of any statute, and the present is an extraordinary situation in which justice requires the requested suspension or waiver.

The fee of \$130.00 as required by 37 C.F.R. §1.17(h) for a petition under 37 C.F.R. §1.183 is attached hereto in the form of Credit Card Payment Form, PTO-2038. If this petition is granted under 37 C.F.R. §1.181 without the necessity of ruling on the §1.183 petition hereof, it is respectfully requested that the fee be refunded. Please charge any deficiency in fees due for consideration and/or granting of this petition to Deposit Account No. 02-4035 of the undersigned.

Statement of Facts Involved

On March 19, 1998, international application number PCT/IL98/00125 was filed designating the United States.

Application number 09/381,358 (the '358 application) was filed on September 20, 1999, as the U.S. national stage application of said PCT/IL98/00125, under 35 U.S.C. §371. In the example beginning at page 42 of the specification of the '358 application, the cloning and isolation of the RAP protein, which binds to the RIP protein, was described. At lines 29-30, a new clone of about 2.2 kB was specified and the DNA sequence and deduced amino acid sequence were set forth.

On July 26, 2001, this 2.2 kB clone was deposited at the Collection Nationale De Cultures Microorganismes (CNCM) at the Institut Pasteur, under accession number I-2706. See the declaration of biological material deposit filed of record in application 09/927,458 on August 7, 2002, a copy of which is attached to the amendment for the '358 application that is attached hereto.

The '358 parent application was expressly abandoned on August 13, 2001, in favor of the CIP application identified in the following paragraph. This was accomplished by way of a statement of express abandonment which appeared in the paper entitled "Response in Parent Case in Support of Petition and Fee for Extension of Time when Filing New Application Claiming Benefit of a Prior Filing" that was filed on August 13, 2001. Such express abandonment was conditional on the CIP receiving a filing date.

A continuation-in-part application claiming the benefit of the '358 application was filed on August 13, 2001, and received application number 09/927,458 (the CIP application). In the description of the example in the CIP application, reference to the above-identified deposit was included. A declaration of biological material deposit and a statement under 37 C.F.R. §1.804(b) were promptly filed on August 7, 2002.

The declaration under 37 C.F.R. §1.804(b), filed on August 7, 2002, in the CIP application, identifies the 2.2 kB RAP clone that was sequenced and disclosed in PCT/IL98/00125, filed March 19, 1998. It states that samples of this clone were placed into storage in the laboratory of Prof. David Wallach, who signed the declaration, and that these samples had been continuously maintained in his laboratory from the date that the clone was originally identified until the date of the declaration, i.e., July 25, 2002. He stated that a sample of this clone, which had been continuously maintained in his laboratory, was deposited as a Budapest Treaty deposit at the Collection Nationale De Cultures Microorganismes of the Institut Pasteur on July 26, 2001, and that this deposit received accession number I-2706. Thus, the declaration concludes that the clone, which he had designated RAP-1, had been under his control since the date it was first identified

prior to the filing of PCT/IL98/00125, until its transfer to the CNCM. This declaration and the accompanying declaration of biological material deposit were accepted by the examiner and the examiner did not object to the reference to this depository accession number in the claims of the CIP application.

Claim 13 of the CIP application presently reads, in pertinent part:

13. An isolated polypeptide which is capable of binding to RIP, which polypeptide comprises:

(a) a RIP-associated protein (RAP) encoded by a DNA sequence in a clone deposited with Collection Nationale De Cultures Microorganismes under accession number I-2706;

....

In an advisory action dated August 19, 2003, in the CIP application, the examiner stated:

As to the effective filing date of instant claims, the instant claim 13 is entitled to the effective filing date of 8/13/01 because the PCT/IL98/00125 filed 3/19/1998 does not have the support for "a RIP-associated" protein (RAP) encoded by a DNA sequence in a clone deposited with Collection Nationale De Cultures Microorganismes under accession number I-2706. In fact, the DNA sequence under accession number I-2706 has 2119 nucleotides, while the DNA sequence encoding RAP in the PCT/IL98/00125 has 2154 nucleotides.

Attached hereto is an amendment for filing in the abandoned '358 application, inserting the information required

by 37 C.F.R. §1.809(d) and submitting the statements required by 37 C.F.R. §1.804(b).

If the formalities required by 37 C.F.R. §1.809 and 1.804 are complied with, the above-identified application will have support for the claim language that the examiner states is unsupported therein.

Points to be Reviewed and Action Requested

(1) It is first requested that the Director review the action of Examiner Huynh in taking the position in the official action of August 19, 2003, that PCT/IL98/00125 does not have support for the protein encoded by the sequence in the deposited clone identified by accession number. Following this review, it is requested that the Director exert his supervisory authority and instruct the examiner to consider that the '358 application, and PCT/IL98/00125, which is a different number for the same application, has support for the deposited clone, as it adequately identifies the biological material, the deposit was made during the pendency thereof, and a statement under 37 C.F.R. §1.804(b) was promptly filed in the continuing application (the CIP application) and must be considered to be equally applicable to the parent application.

(2) If the first ground of relief cannot be granted, it is requested that the director order entry of the attached amendment and supporting papers in the file of the abandoned

parent '358 application. It is further requested that the director instruct the examiner to consider that in light of the entry of the amendment and declarations attached hereto into the '358 application, that the '358 application is in full compliance with all applicable regulations, so that support for claim language incorporating the depository accession number cannot be denied on this basis.

(3) If neither of the first two requested grounds of relief can be granted, it is requested that the requirement of 37 C.F.R. §1.809(e) that any amendment required by 37 C.F.R. §1.809(d)(1), (d)(2) or (d)(4) be filed before or with the payment of the issue fee be suspended or waived, if necessary, and that the requirement of 35 U.S.C. §1.804(b) that the required statements be "promptly" submitted be waived or suspended, if necessary, and that any other requirement of the regulations that might prevent its entry be suspended or waived, so that the attached amendment can be made of record in the abandoned '358 application, thereby providing support for the claims of the CIP application.

Argument

The '358 Application Provides Support for Claim 13 of the CIP Application without the Necessity for any Amendment Thereof

The present petition arises with respect to a position that the examiner has taken in CIP application 09/927,458. In

that case, the examiner has stated that the claims recite a depository accession number, but there is no support for such an accession number in the parent case. However, the parent case describes the same biological material as was described in the CIP and was eventually deposited. Furthermore, the parent application could have been amended prior to its abandonment to insert reference to the depository number, as is specifically permitted by 37 C.F.R. §1.804.

37 C.F.R. §1.804(a) provides that whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made, subject to §1.809, during pendency of the application for patent. Here, the biological material was specifically identified (the 2.2 kB RAP clone) in the parent application as filed, i.e., when the International Application was filed, and the deposit was made during the pendency of the '358 application.

The only requirement of 37 C.F.R. §1.804(b) is that once a post-filing deposit is made, a statement be promptly submitted from a person in a position to corroborate the fact, stating that the biological material that was deposited is a biological material specifically identified in the application as filed. Such a statement was promptly submitted and is of record in the CIP application. Thus, all of the requirements of

37 C.F.R. §1.804(a) and (b) have been complied with except, one could argue, for the requirement to comply with 37 C.F.R. §1.809 and the requirement that the statement be "promptly" submitted.

As to the requirement to "promptly" submit a statement, as set forth in §1.804(b), there is no explicit requirement that the statement be filed in every application for which priority is claimed. If the reference to the deposit is first made in a continuing application and the statement is promptly filed thereafter in the continuing application, and the statement expressly states that the biological material which is deposited is a biological material specifically identified not only in the continuing application but also in the parent application, then such a statement as filed in the continuing application should be considered as effectively complying with the requirement of 37 C.F.R. §1.804(b) also with respect to the parent application.

It exalts form over substance to require that the same statement also be filed in the parent case, which has already been abandoned, when it is apparent from its face that it is also applicable to the parent case. There is nothing on the face of §1.804 which would prevent a statement filed in a continuing application from being considered to be applicable also to the abandoned parent application even though not physically filed therein.

The Attached Amendment to the '358 Application Places the '358 Application into Full Compliance with 37 C.F.R. §§1.804 and 1.809 without the Necessity of the Suspension or Waiver of any Regulation

With respect to §1.809, which is incorporated into §1.804(a), §1.809(d) states that for each deposit made pursuant to these regulations, "the specification shall contain" a number of requirements. This requirement should be interpreted as applying only to the specification of the patent that issues. This is made apparent by 37 C.F.R. §1.809(e), which refers to the fact that the amendment should be made before or with the payment of the issue fee.

Accordingly, the Director should rule that the claim language of the CIP application is supported by the '358 application, even without an amendment to the specification of the '358 application. The requirements of 37 C.F.R. §1.809(d) and (e) should apply to the entire chain of continuing applications, and not be interpreted as requiring literal compliance in every application of that chain.

Attached hereto is an amendment to the specification of the abandoned '358 application and a submission of a declaration of biological material deposit and a declaration complying with 37 C.F.R. §1.804(b). This declaration should be accepted has having been substantially "promptly" submitted after receipt of the examiner's action of August 19, 2003, first advising applicants that the claim was not entitled to the

effective filing date of the parent application because of the absence of a reference to the biological material deposit, notwithstanding the fact that a statement under 37 C.F.R.

§1.804(b) had been filed and accepted in the CIP application.

Accordingly, the declarations filed on even date herewith can be considered to have been "promptly" submitted as required by 37 C.F.R. §1.804(b) without the necessity of waiving any rule.

Furthermore, to the extent that is considered necessary that the specification of the parent application be amended in the manner specified in §1.809(d), the amendment which is attached hereto places the parent application into compliance. It has been held that an amendment may be entered in an abandoned application for purposes other than prosecution. See *Sampson v. Comm'r of Patents*, 195 USPQ 136 (DDC 1976).

37 C.F.R. §1.809(e) requires that any such amendment be filed before or with the payment of the issue fee. The attached amendment is in compliance with this regulation, as no issue fee has yet been paid in the abandoned '358 application. Thus, the present amendment cannot be said to be untimely.

If Necessary, the Interests of Justice Require Waiver of any Regulation that Might Otherwise Prevent Either of the First Two Requested Grounds of Relief

If none of the above-requested grounds for relief are considered grantable, then it is requested that any requirements of the patent regulations which prevent the acceptance of the

amendment or otherwise prevent the Director from ruling that the claimed reference to depository number I-2706 is entitled to the effective filing date of the parent, be waived or suspended pursuant to 37 C.F.R. §1.183. Thus, if the filing of the statement on even date herewith is not considered to comply with the "promptly" requirement of 37 C.F.R. §1.804(b), this requirement should be suspended or waived pursuant to 37 C.F.R. §1.183, because there is no statutory requirement for promptness. The reason why the statement was not filed during the pendency of the parent case is because a CIP was filed and the '358 application abandoned before the statement could be prepared; the statement was promptly filed in the CIP application. Again, the deposit was made during the pendency of the '358 application.

Similarly, to the extent the requirement of 37 C.F.R. §1.809(e) is intended to require that the amendment be made during the pendency of the parent application, it is respectfully requested that this requirement be suspended or waived pursuant to §1.183.

The present situation is extraordinary, and the interests of justice require the suspension or waiver of these requirements because to do otherwise would create an anomalous situation to the substantial disadvantage of and with substantial prejudice to applicants. The exact same situation

could have arisen if the present application were a continuation of the parent with the exact same specification. The specification of the continuation could have been amended to add reference to the deposit, a §1.804(b) declaration submitted, and the exact same claim presented. It would be an anomalous and unintended situation if a claim would be considered to be supported by a continuation application, but not supported by a parent filed with the exact same specification. Certainly, such an anomalous situation would never have been intended by the rules. Accordingly, this extraordinary step of amending the parent case to provide support for the same language appearing in the continuing application is being taken. This is an extraordinary situation and the interests of justice require that this request be granted.

The Discrepancy in the Length of the DNA Sequence Noted by the Examiner Is Irrelevant to the Issues Presented Here

One of the reasons given by the examiner for refusing to grant the CIP the effective filing date of March 19, 1998, is that the DNA sequence provided for the DNA sequence in the clone deposited under I-2706 has 2,119 nucleotides, while the DNA sequence encoding RAP in the '358 application has 2,154 nucleotides. This is one of the reasons why applicants consider it necessary to have the effective filing date for the actual biological material originally obtained and subsequently

deposited, to be the same as the international filing date of the '358 application. A sequencing error occurred so that the sequence in the '358 parent application was not accurate. Only by depositing the actual biological material so that anyone can obtain it and determine the correct sequence, can the sequencing error be corrected or made irrelevant.

However, the existence of a sequencing error in the parent application is not relevant to any of the issues presented in this petition. The evidence of record, in the form of the Declaration under 37 C.F.R. §1.804(b), is that the biological material actually reported in the '358 parent application is the same material that was deposited under deposit accession no. I-2706. Once it is established that there is support in the '358 application for this deposited clone, then prosecution can ensue, if necessary, on the substantive issue as to whether or not the correction of the nucleotide sequence is new matter or affects the effective filing date of a claim that refers only to the sequence of the deposited clone and not any specific SEQ ID NO. The fact that the sequence has already been corrected in the CIP application does not preclude applicants from being entitled to establish support for the deposited material in the '358 parent application.

Conclusion

The examiner erred in ruling that a claim having reference to a depository number cannot be supported by a parent application which does not explicitly reference that depository number. The parent application identifies the same biological material as is identified in the continuing application. The declaration under 37 C.F.R. §1.804(b), as filed in the continuing application, refers to that biological material and establishes that the biological material is the same as the biological material specifically identified in the parent application as well as in the continuing application. Finally, the specification of the continuing application complies with 37 C.F.R. §1.809(d) and (e). Hence, the deposit of the biological material during the pendency of the parent '358 application and the reference to the deposit and the §1.804(b) statement made in the CIP should be imputed to the parent application. Furthermore, the reference to the biological material in the parent '358 application should be considered as being equivalent to the recitation of the deposit in the CIP application. Therefore, the CIP should be accorded the benefit of priority of the parent '358 application vis-à-vis the biological material disclosed in the parent case. Support should not be denied on the technicality that the deposit number is not explicitly in the specification of the parent. Accordingly, the Director

Accordingly, the Director should instruct the examiner to consider the recitation of the biological material in the parent case to effectively refer to the depository number, in light of the §1.804(b) declaration of record in the CIP, so that support for the claim language cannot be denied on this basis.

To the extent that it is determined that a physical amendment to the parent case is necessary, an amendment is attached hereto for entry into the '358 application. This amendment can, and should, be entered into the '358 application so as to provide literal support for the claim language which the examiner has previously found not to be supported in the parent application. Accordingly, the Director should order the entry of the attached amendment into the file of the abandoned '358 application and should instruct the examiner to consider that the recitation of the depository accession number in the '358 application is in full compliance with all applicable regulations, so that support for the claim language of claim 13 of the CIP application cannot be denied on this basis.

If 37 C.F.R. §1.804(b) is interpreted as precluding entry of the statement into the record of the parent case because it was not "promptly" submitted, the extraordinary circumstances of this case warrant a suspension or waiver of the requirement for promptness, so as to permit the submission of such a statement into the record of the '358 application. If 37

C.F.R. §1.809(e) is interpreted as requiring that the amendment to the specification be filed during the pendency of the application, then the same extraordinary circumstances warrant suspension or waiver of this requirement, so that the amendment attached hereto can be entered into the record of the '358 application. Once entered, the reference to the deposit in the parent application will fully comply with all applicable regulations and will therefore provide support for a recitation of that depository number in the CIP application.

Accordingly, the Director should suspend or waive any applicable regulation that would prevent acceptance of the papers filed in the CIP application from effectively serving to comply with the applicable regulations also for the '358 application.

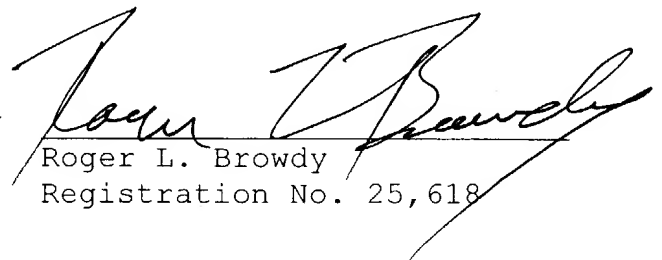
Alternatively, the Director should suspend or waive any applicable regulation that would prevent entry of the attached amendment in the abandoned '358 application, or would prevent the attached amendment from effectively serving to comply with the applicable regulations. The Director should instruct the examiner to consider that the recitation of the depository accession number in the '358 application is in full compliance with all applicable regulations, so that support for the claim language of claim 13 of the CIP application cannot be denied on this basis.

Accordingly, suspending or waiving applicable regulations, if considered necessary, authorizing entry of the attached amendment into the abandoned '358 application if considered necessary, and instructing the examiner to consider recitation of the specific depository number for the 2.2 kB RAP clone to be supported by the disclosure of the parent application as of the international filing date thereof (the '358 application being a \$371 national stage application), are earnestly solicited.

Respectfully submitted,

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